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EXAMINER

HM32/0105

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | 9 |

DATE MAILED: 01/05/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 16 October 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 1-45 is/are pending in the application.
Of the above, claim(s) 31-45 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-30 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5, 7
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

## DETAILED ACTION

**1.** Applicants' Response to Restriction Requirement, paper#8, received 16October1998, is acknowledged. Applicants elect, without traverse, Group I, Claims 1-30, drawn to a method of identifying compounds which inhibit pathogens. Claims 31-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

**2.** Currently, claims 1-30 are under consideration.

### Drawings

**3.** This application has been filed with drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. The drawings are objected to for the reasons set forth on the attached form PTO-948.

### Specification

**4.** The disclosure is objected to because of the following informalities:

a) page 8, line 7, "strains" should be "strain",

b) page 65, line 12, "loose" should be "lose",

Appropriate correction is required.

### Double Patenting

**5.** A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg.*

*Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

**6.** Claims 1-14, and 20-30 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-25 of copending Application No. 08/852,927. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

**Claim Rejections - 35 USC § 112**

**7.** Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying a compound capable of inhibiting a pathogen by exposing said pathogen to said compound, does not reasonably provide enablement for identifying a compound capable of inhibiting a pathogen by exposing another pathogen to said compound . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

The instant claims are directed to identifying a compound capable of inhibiting **a** pathogen by exposing eukaryotic organisms to **a single** pathogen in the presence of **at least one candidate** compound, and identifying **a** compound.

The claims do not restrict the identification of **a** compound by testing **said** compound, but the scope of the claims encompass such identification by testing **any other** compounds.

The claims do not restrict the testing to the same pathogen, but the "a single" pathogen to which the at least two different eukaryotic organisms are exposed may be different from the pathogen of the preamble of claim 1.

**8.** Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying a compound capable of inhibiting a pathogen in a eukaryotic organism by infecting eukaryotic organisms susceptible to said pathogen with the pathogen in the presence of said compound, does not reasonably provide enablement utilizing all other eukaryotic organisms as the infection model. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of the instant encompasses identification of a compound capable of inhibiting Herpes simplex virus in humans by "exposing" lettuce and celery to the virus in the presence of a candidate compound. However, the specification does not teach that Herpes simplex virus infects/multiplies in such plants. Thus, the specification only teaches the use of pathogens and eukaryotic organisms which have been shown to exhibit such a host/infection relationship.

**9.** Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear which "said pathogen" is referred to in claim 1, the pathogen of the preamble, or the "a single pathogen".

It is indefinite what is meant by "exposing" eukaryotic organisms to a single pathogen. Suggested terminology would be "infecting at least two different eukaryotic organisms".

It is unclear from what the "at least two different" eukaryotic organisms are different. Are they different from the eukaryotic organism of the preamble of claim 1 or different from themselves.

**Claim Rejections - 35 USC § 103**

**10.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**11.** Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Elrod et al (*J. Bacteriol.*, 46:633-645, 1942) or Schroth et al (*Pseudomonas aeruginosa: Ecological Aspects and patient Colonization*, pages 1-29, 1977) in view of Kominos et al (*Appl. Microbiol.*, 24(4):567-570, 1972) and further in view of Geels (*J. Appl. Bacteriol.*, 79:38-42, 1995) and in further in view of Conrad et al (*Rev. Inf. Dis.*, 13, supplement 7:S634-639, 1991).

Elrod et al teach pathogenicity across plant and animal barriers. Specifically, Elrod et al identify a pathogen, *Pseudomonas aeruginosa*, that infects humans(page 633, last paragraph) as well as plants (section *Phytopathogenicity of Pseudomonas aeruginosa*, pages 639-641). It was noted that various strains of this bacterium had lost their pathogenicity for animals, but they had retained the ability of attacking plant tissues (page 641, paragraph 1). Therefore, Elrod et al teach

the use of plant virulence models, as well as animal models for the same pathogen for the study of virulence of a pathogen. In addition, Elrod et al teach that *P. aeruginosa* serves a dual pathogen role, infecting animals and plants, thus teaching that for such dual pathogens, utilizing both animal and plant models is known.

Schroth et al teach the pathogenicity across plant and animal barriers. Specifically, Schroth et al teach that *Pseudomonas aeruginosa* infects patients in hospitals as well as agricultural plants (page 1, first paragraph; Table 1; section **Pathogenicity of P. aeruginosa in Plants**, page 16-22).

Kominos et al teach that vegetables are an important source and vehicle by which *P. aeruginosa* colonizes the intestinal tract of patients (Abstract; section **Isolation of P. aeruginosa from vegetables**, page 567-568; Table 2; Table 3).

Thus, the teachings of Elrod et al, Schroth et al, and Kominos et al indicate that *P. aeruginosa* is a pathogen frequently involved in disease in both plants and animals. Because of this, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to test drug efficacy of a variety of suspected compounds for controlling or eradicating the presence of *Pseudomonas* sp. or *P. aeruginosa* strains in both plants and animals. As such, it also would have been obvious at the time the invention was made to a person having ordinary skill in the art to utilize models of both plants and animals in order to identify those compounds which work best in plants and/or animals.

Conrad et al teach human clinical models to identify a compound (aztreonam) which is efficacious for treatment of a pathogen (*P. aeruginosa*) (Abstract; section **Patients and Methods**, page 634-636).

Geels teaches a plant model to identify a compound (kasugamycin) which is efficacious for treatment of a pathogen (*P. tolaasii*) (Abstract; section **Materials and Methods**, page 38-39)

**Conclusion**

**12.** No claims are allowed.

**13.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703)308-4027. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

Rodney P. Swartz, Ph.D.
Patent Examiner
Art Unit 1641
January 4, 1999